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TEST AND EVALUATION OF THE BIPRESS UNIVERSAL INFUSION DEVICE

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Final Technical Report for January 1996 to April 1996

ARMSTRONG LABORATORY

AIR FORCE MATERIEL COMMAND
BROOKS AIR FORCE BASE, TEXAS

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This report has been reviewed and is approved for publication.

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Bipress Inc. approached Aeromedical Research requesting airworthy evaluation for their product, the Bipress Universal Infusion Device. The company felt they had developed a product to enhance I.V. fluid infusion without the aid of gravity, which would decrease the number of personnel or support devices needed during patient transport.

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TESTING AND EVALUATION OF THE BIPRESS UNIVERSAL INFUSION DEVICE

BACKGROUND

Bipress Inc. approached Aeromedical Research requesting airworthy evaluation for their product, the Bipress Universal Infusion Device. The company felt they had developed a product to enhance I.V. fluid infusion without the aid of gravity, which would decrease the number of personnel or support devices needed during patient transport.

DESCRIPTION

The Bipress Universal Infusion Device, hereafter known as Bipress, is a portable I.V. infuser designed to deliver blood and other fluids contained in flexible bags of up to one liter capacity. Its special design enables the Bipress to infuse fluids to the patient regardless of patient body position, lying or upright, by use of air pressure and maintaining the drip chamber in a vertical position. The device eliminates the need for an I.V. pole or an extra person to hold the fluid bag. In addition, the Bipress is equipped with straps to allow use of the device by ambulatory patients. Bipress can be adjusted to deliver a fast infusion of blood or solution under pressure and continuous drip mode. Precise drip rate is difficult to achieve and Bipress recommends frequent monitoring during extended use.

Figure 1. Bipress Universal Infusion Device

PROCEDURES

Test methods and performance criteria were derived from various military standards (Reference List 1), nationally recognized performance guidelines (2), and manufacturer's literature (3). The Aeromedical Research Procedures Guide describes safety and human factor issues to be considered during equipment testing (4). A test setup and performance check were developed to verify proper functioning of the equipment under various conditions.

The device was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Altitude
    a. Cabin Pressure/Altitude
    b. Rapid Decompression to Ambient
4. Environmental, encompassing:
    a. Hot Operation
    b. Cold Operation
    c. Humidity
    d. Hot Temperature Storage
    e. Cold Temperature Storage
5. Airborne Feasibility

Test Setup

A test setup was assembled for functional evaluation of the Bipress Universal Infusion Device.

a. The Bipress was connected to a flexible 1000 ml IV bag filled with sterile water. An IV tube with drip chamber was connected to the IV bag, with the other end connected to a manual collection vessel or through an Infutest 2,000 infusion analyzer to a collection vessel.

b. Performance Check was used to quantitatively measure and record Bipress performance during standard ambient conditions before adverse testing. The performance check was used as a reference to measure subsequent performance. It initially verified manufacturer specifications and checked for safe operation before testing.

Performance Check. The test consisted of the following:

1. Insert a flexible 1000 ml IV bag filled with sterile water into the right-handed inflatable pocket.
2. Connect IV tubing with drip chamber (10 gtts/ml) into the flexible IV bag.

3. Connect the other end of IV tubing to flexible collection bag through the inlet port.
4. Close both quick pressure discharge valves.
5. Pump left-hand pocket on Bipress to 0.2 bars.
6. Adjust regulator to pressure the right-hand pocket to 0.2 bars of pressure, (may have to add more pressure to left-hand pocket to pressure the right-hand pocket with desired pressure).
7. Set rate at approximately 60 to 125 cc/per hour.
8. To test left-hand pocket repeat the above steps.

A complete test and gauge accuracy check was performed and recorded before and after each laboratory test. During each laboratory test a complete test was accomplished and the parameters were recorded. Values derived from pretest recordings were used as a baseline reference in determining variation in results during each portion of testing. Post-performance check values were used to identify any deviation from the pre-performance check values which might indicate damage to the unit's internal components as a result of testing.

Initial inspection

The initial inspection checked for obvious damage to the unit during shipping. It was an operational verification comparing the Bipress's operating characteristics (i.e., gauge pressure, bladder integrity) to displayed parameters. These operating characteristics were measured, recorded, and compared to the manufacturer's published specifications.

Vibration

These evaluations were designed to determine an item's construction, durability, and performance during worst case scenario vibrations. The Bipress was subjected to vibration tests in accordance with MIL-STD-810E. Tests consisted of random (11 Hz to 2,000 Hz) and sinusoidal (5 Hz to 500 Hz) curves on X, Y, and Z axes. During sinusoidal tests, the Bipress was inflated and vibrated for 5 sweeps of 15- minute duration (for a total of 75 minutes) on each axis. During random tests, the Bipress was inflated and vibrated for 30 minutes on each axis. Before and after each axis, a visual examination of the unit was performed and measurements were recorded.

During vibration testing the Bipress was secured to the vibration table using a NATO Litter simulator and the Bipress unit strap.

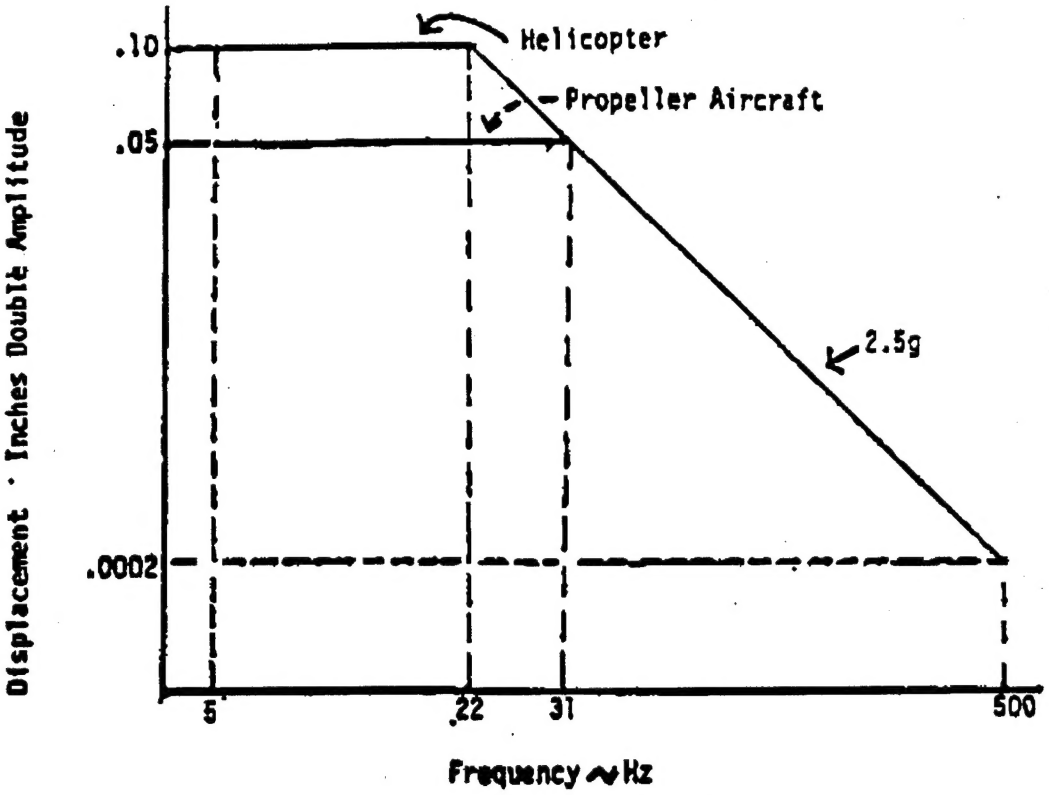

Figure 1 - Sinusoidal Vibration Test Curve

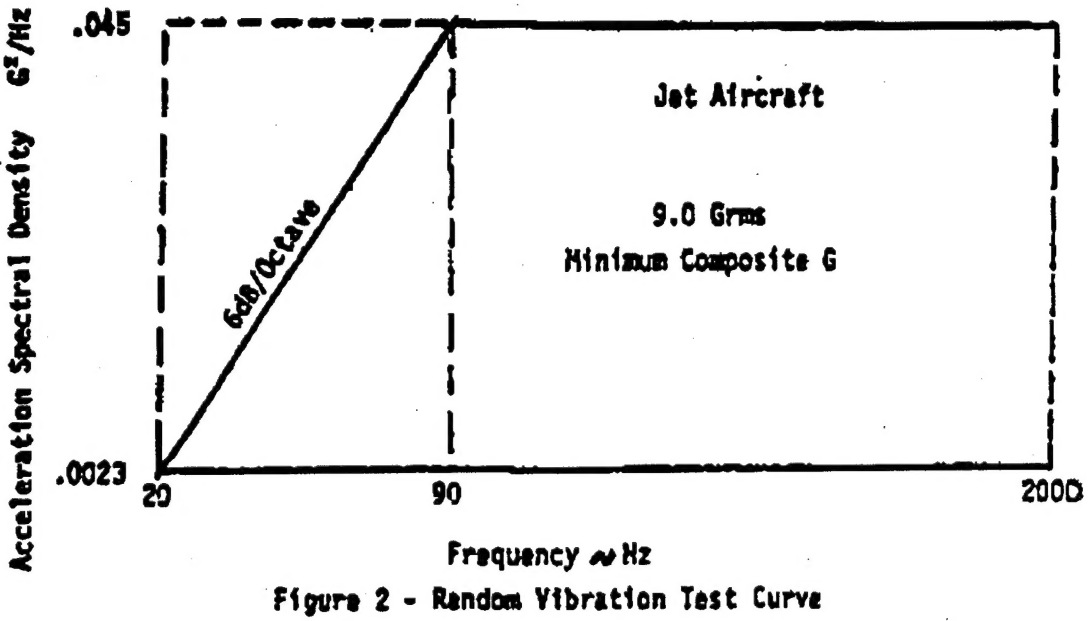

Figure 2 - Random Vibration Test Curve

Figure 2. Category 10, figures 514.4-16 and 514.4-17 of MIL-STD-810E

Altitude

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operation personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

a. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin to barometric pressures equivalent to 8,000-10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the Bipress while ascending from ground level to 10,000 ft, maintaining altitude for one hour, and then descending back to ground, at a rate of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompression is caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to determine how medical equipment will function during and after such a decompression and ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The Bipress operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft briefly, and then brought back down to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The Bipress was monitored throughout the series of decompressions, to include performance checks and unit recoverability each time the unit returned to ground level.

Environmental

Environmental test conditions were tailored (based on the aeromedical operational environment) from MIL-STD-810E. These tests measured the system's performance under varying temperature and humidity conditions encountered during transport. A complete Baseline Performance test was performed prior to starting and at the end of each test period. The Bipress was placed inside the environmental chamber. At the end of each storage test, the chamber was dehumidified and the temperature adjusted to 20°C (75°F) to return it to existing ambient conditions. The Bipress remained inside the chamber for 30 minutes. During the post test stabilization period, post test measurements were taken. For operational testing, the unit was evaluated in the chamber while inflated and its ability to infuse fluids was monitored. Following is a list of environmental test parameters.

Hot Temperature: Operation: 49° C ± 2° C (120° F ± 3.6° F) for 2 hours.
Storage: 60° C ± 2° C (140° F ± 3.6° F) for 6 hours.

Cold Temperature: Operation: 0° C ± 4° C (32° F ± 7.2° F) for 2 hours.
Storage: -40° C ± 2° C (-40° F ± 3.6° F) for 6 hours.

Humidity: Operation: 94 ± 4 % relative humidity 29.5° C ± 2° C (85° F ± 3° F) for 4 hours.

Airborne Feasibility

Inflight feasibility tests were conducted to develop and/or verify medical equipment operating procedures and to validate operational performance of the equipment in the actual aeromedical evacuation environment. Setup, securing methods, and integration with aircraft systems were evaluated. The flight crew was encouraged to participate, and their comments were documented and included in this evaluation. Inflight testing was conducted on the C-130H aircraft.

RESULTS

Initial Inspection

Initial inspection revealed a structural problem related to the way the internal bladders were manufactured. Bladders ruptured during initial bench testing. Also noted was the inability to secure IV containers in case of internal bladder rupture. Following identification of this problem, the company modified the bladders, changed to a different type of polymer compound and stopped using talc as a lubricant in the bonding process. Bipress also added elastic securing straps with locking clips. Aeromedical Research accepted the Bipress units with the green internal bladders using the new polymer and the addition of elastic securing straps with locking clips for use in USAF aeromedical aircraft.

Vibration

The Bipress functioned per manufacturer's specifications during vibration testing.

Altitude

1. Cabin Pressure/Altitude: As altitude levels increased so did the Bipress's internal bladder pressure. However, the fluid rate did not increase from preset rate. During descent the Bipress internal pressure recovered and lost 0.02 bar of pressure. The

Bipress performed within acceptable limits. Aeromedical Research recommends monitoring function of the device during all phases of flight.

2. Rapid Decompression: During all three test phases the Bipress expanded and the pressure gauges registered maximum levels, however, the unit did not rupture. Minimal increase in infusion rate was seen, and the unit recovered with some loss of pressure after recovery (0.02 - 0.06 bar). Aeromedical Research considers the device acceptable for use. Intravenous standards require monitoring of the device upon reaching a safe cabin altitude.

Environmental

The Bipress operated well during all phases of testing. The unit underwent Hot Storage & Operation, Cold Storage & Operation and Humidity at Bldg. 160, Brooks AFB TX. The Bipress passed all environmental guidelines.

Airborne Feasibility

This evaluation confirmed that the Bipress will successfully operate in aeromedical evacuation aircraft.

RECOMMENDATIONS

1. Monitor function of the device during all phases of flight.
2. Provide instructions to inform users of the following: "As fluid levels in flexible containers decrease the pressure valve will need to be readjusted to maintain infusion rate at preset levels." In Addition, changes in barometric pressure will affect the IV infusion rate.
3. Carry an extra bladder due to the possibility of bladder rupture.
4. Use elastic securing straps with locking clips to hold IV bags in place in the event the unit experiences pressure loss.
5. Use **"ONLY"** the green internal bladders made with the new polymer.

Figure 3. Bipress with I.V. Bag securing device

REFERENCES

1. MIL-STD 810-E, "Environmental Test Methods and Engineering Guidelines"

2. Emergency Care Research Institute (ECRI), INDEX 1995

3. Bipress Universal Infusion Device Operating Instructions.

4. Aeromedical Research Procedures Guide, Internal Operating Instruction, Armstrong Laboratory, Systems Research Branch.

APPENDIX A

APPENDIX

SPECIFICATIONS AND OPERATING FEATURES OF THE BIPRESS UNIVERSAL INFUSION DEVICE

Model: Bipress

Manufacturer: Bipress, Inc.
1680 Meridan Ave
Miami Beach, Florida 33139
Phone: (305) 442-8202

Size Unfolded: 45 cm X 31 cm

Size Folded: 31 cm X 17 cm

Approximate Unit Weight: 900 g.